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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,350	10/11/2001	Martin J. Jacobs	CP215	9510

27573 7590 09/21/2005

CEPHALON, INC.  
41 MOORES ROAD  
PO BOX 4011  
FRAZER, PA 19355

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/975,350	JACOBS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 7-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-58 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

5-20

### DETAILED ACTION

Examiner acknowledges request for change of address filed 02/15/05; request for extension of time, amendment and remarks filed 07/08/05. Claims 1-5 and 7-58 are pending.

### *Claim Rejections - 35 USC § 112*

#### NEW MATTER

1. Claims 55-57 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reciting the levo-form of modafinil. Although US 4,927,855, which talks about levorotatory modafinil, is incorporated in its entirety by reference, it is noted that in the specification at paragraph 26 of the published application, it is stated "as used herein, "a modafinil compound" or "modafinil compound" and the like, refers to **modafinil, its racemic mixtures, individual isomers**, acid addition salts, such as a metabolic acid of modafinil, benzhydrylsulfinylacetic acids, and its sulfone forms, hydroxylated forms, polymorphic forms, analogs, derivatives, congeners and prodrugs thereof. Prodrugs are known in the art as compounds that are converted to the active agent (a modafinil compound) in the body of a subject. In certain preferred embodiments, the modafinil compound is modafinil. However, the rejection is withdrawn to the extent that the "individual isomers" cover the levo- or dextro-forms of the modafinil.

2. Claims 1-5 and 7-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Page 2, lines 19-25 of the instant specification and paragraph 7 of the published application in the background states “a technique recently developed to formulate liquid pharmaceutical compositions for agents that display very low water solubility involves a self-emulsifying drug delivery system, known as "SEDDS". These drug delivery systems are isotropic mixtures of lipids or lipid-soluble compounds and a surfactant that rapidly form thermodynamically stable microparticles upon contact with water. See, e.g., Shah et al., International Journal of Pharmaceutics (Netherlands), 106:15-23, (1994), which is incorporated in its entirety herein by reference.

Although, the Shah reference is incorporated by reference, there is no further mention of self emulsifying system. The recitation of a self emulsifying system is new matter.

***Claim Rejections - 35 USC § 102***

3. Claims 1-4, 32, 33, 36, 37, 39, 41-44, 47, 48, 51, 52, 54 and 58 remain rejected under 35 U.S.C. 102(b) as being anticipated by Grebow et al. (US 5,618,845).
4. Applicants' arguments filed 07/08/05 have been fully considered but they are not persuasive.

The argument that Grebow fails to disclose a self emulsifying drug delivery system is not persuasive a “self emulsifying drug delivery system” is an isotropic mixtures of an oil and non-ionic emulsifier (Shah et al.) or isotropic mixtures of oil and surfactant (Charman et al.) which form fine oil-in-water emulsion when introduced to aqueous phases with only gentle agitation. Grebow discloses modafinil particles in suspension or emulsion.

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5. Claims 1-4, 7, 11, 14, 15, 32, 33, 36, 37, 39, 47, 51 and 54 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nguyen et al. (US 5,843,347).

6. Applicants' arguments filed 07/08/05 have been fully considered but they are not persuasive.

The argument that Nguyen fails to disclose a self emulsifying drug delivery system is not persuasive because a "self emulsifying drug delivery system" is an isotropic mixtures of an oil and non-ionic emulsifier (Shah et al.) or isotropic mixtures of oil and surfactant (Charman et al.) which form fine oil-in-water emulsion when introduced to aqueous phases with only gentle agitation. Nguyen discloses modafinil particles in suspension or emulsion or oil-water emulsion (column 5, lines 55-65; column 7, lines 27-30).

***Claim Rejections - 35 USC § 103***

7. Claims 17, 18, 34, 35, 38, 45, 46, 49, 50 and 53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845).

8. Applicants' arguments filed 07/08/05 have been fully considered but they are not persuasive.

Grebow's formulation is an emulsion or suspension and applicants' argument that the emulsion of Grebow differs from applicants emulsion is not persuasive because the self emulsifying system forms emulsion when brought in contact with water and the formulation of Grebow forms an emulsion.

9. Claims 8-10, 13, 17-20, 34, 35, 38 and 40-46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Lafon (US 5,180,745).

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10. Applicants' arguments filed 07/08/05 have been fully considered but they are not persuasive.

Isotropic is a descriptive of the property of transmitting light and if the claimed modafinil is isotopic, then the disclosed modafinil of the prior art also has that property. Lafon is relied upon for a teaching/disclosure that Modafinil is used to treat Parkinson disease and not on the form of the modafinil formulation. Nguyen does not disclose crystalline modafinil. Nguyen discloses suspension/emulsion. Nguyen discloses emulsion of modafinil formulation and therefore, the rejection is proper.

11. Claims 55-57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845) in view of Lafon (US 4,927,855).

12. Applicants' arguments filed 07/08/05 have been fully considered but they are not persuasive.

Applicants' argument that the emulsion of Grebow differs from the self emulsifying drug system is not persuasive because the self emulsifying system forms an emulsion when brought in contact with water, and the formulation of Grebow is an emulsion.

### ***Double Patenting***

Examiner acknowledges applicants' recognition of the obviousness type double patenting rejection and applicants' willingness to file a terminal disclaimer when allowable subject matter is identified. However, the rejection is maintained. Claims 1, 3-5, 14, 15, 32-35 and 44 remain rejected under the judiciary created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 8, 10-13, 26-29, 31 and 32 of US 6,489,363 for reasons stated in the previous rejected mailed 01/11/05.

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13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara  
Patent Examiner  
Tech. Center 1600

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
CENTER 1600